

For CIC Consideration

April 5, 2002 request received:

Simultaneous evaluation of all the statins by the CIC.

Status of Lovastatin

February 1999

- prioritized as “high” carcinogenicity concern
- selected for preparation of hazard identification document
- Request for Relevant Data *CRNR*

Today

- Draft in preparation

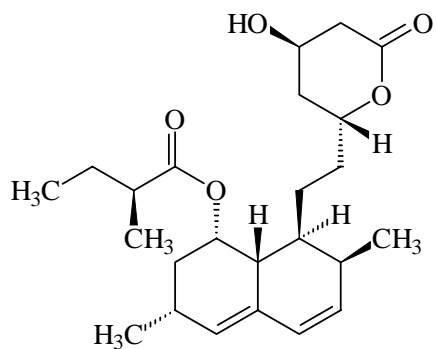
Status of other statins

Statins, including Pravastatin Sodium,
Simvastatin, Fluvastatin Sodium,
Atorvastatin Calcium, Cerivastatin Sodium

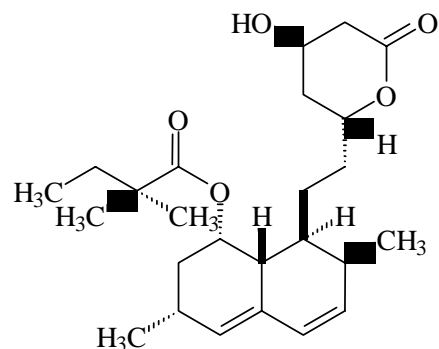
- Not yet selected for prioritization

Statins: Widely prescribed drugs with lipid-lowering effects

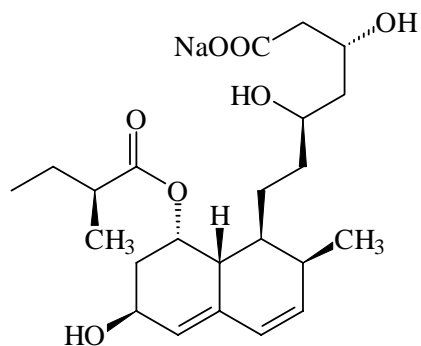
- Inhibit HMG-CoA reductase, an early rate-limiting step in cholesterol biosynthesis.
- Reduce total cholesterol, LDL cholesterol, apolipoprotein B, triglyceride levels
- Increase HDL cholesterol



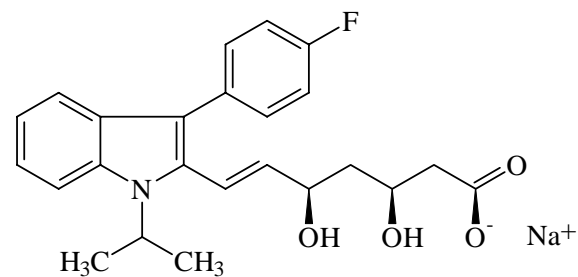
Lovastatin



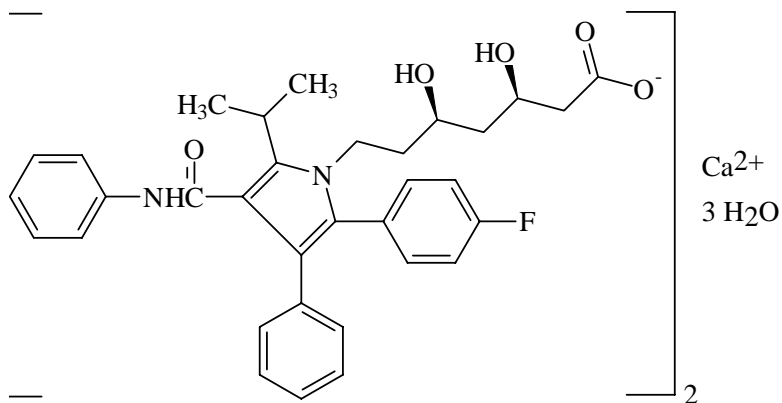
Simvastatin



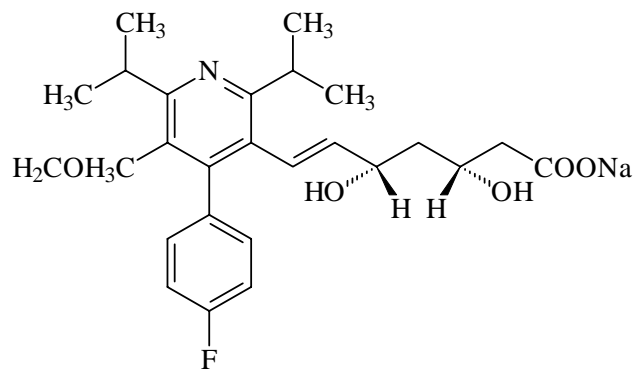
Pravastatin sodium



Fluvastatin sodium



Atorvastatin calcium



Cerivastatin sodium

Statins and Tumors in Animals, as reported in U.S. FDA-approved product labels

	Atorva-	Ceriva-	Fluva-	Lova-	Prava-	Simva-
Liver	FM, MM	FM, MM		FM, MM MR	MR MM, FM	FM, MM MR, FR
Thyroid			MR	R		FR
Lung				FM	FM	FM, MM
Fore- stomach			FM, MM	FM		
Harderian Gland						FM, MM
Muscle	FR					

Summary

- OEHHA currently completing HID on lovastatin
- Widespread, long-term exposure to statins
- Structural, pharmacologic, and toxicologic similarities
 - Multiple tumor sites in common
- Common mechanism of carcinogenicity likely

